DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1125B

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 23 1997

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Andreas Hahn
V.P., General Manager
Stockert Instrumente, GmbH
Lillenthalalee 5-7
Munich, Germany D-80939

Dear Mr. Hahn:

During an inspection of your facility located at Stockert Instrumente, GmbH, facility in Munich, Germany, from November 18-21, 1996, our investigator observed conditions which are serious violations of the United States' Federal Food, Drug, and Cosmetic Act (the Act) and deviations from implementing regulations as follows:

> The devices manufactured by your firm are adulterated within the meaning of Section 501(h) of the Act because the methods used in, and the facilities and controls used for the manufacturing, packaging, storage, or installation of devices are not in conformance with the Good Manufacturing Practices (GMP) for Medical Device Regulations as prescribed by Title 21, Code of Federal Regulations, Part 820, as follows:

1. Failure to adequately calibrate all production and quality assurance measurement equipment, as required by 21 CFR 820.61. For example, not all heart lung machine production and quality assurance measurement equipment is routinely calibrated according to written procedure. More than 80 pieces of electrical and mechanical equipment are not routinely calibrated. Specific examples are:

   a. Tektronix oscilloscope #MG149;

   b. Uniwatt Elektronische Last EL1000 instruments #MG201 and #MG213;

   c. Lutron DM 6023 Capacitance Meter #MG142;

d. Metriso 5000 ABB Metrawatt #MG203;

e. Jaquet Tachometer, Type DHO 907, serial no. 3392200018; and

f. various custom made precision resistors.

2. Failure to establish and implement specification control measures to assure that the design basis for the device, and packaging is correctly translated into approved specifications, as required by 21 CFR 820.100(a)(1). For example:

a. There is no documentation to show the process used to wave solder 27 different types of S3 heart lung machine printed circuit boards has been validated to operational limits.

b. Tolerances have not been established for solder temperature, flux flow, preheat zone temperature, and conveyer speed specifications.

c. The procedure used for burn-in does not specify the room temperature at which this operation should be conducted. Burn-in temperature recordings showed a wide temperature fluctuation.

3. Failure to have written procedures describing any processing controls necessary to assure conformance to specifications, where deviations from device specifications could occur as a result of the manufacturing process itself, as required by 21 CFR 820.100(b)(1). For example, there are no written procedures for using the ERSA machine.

4. Failure to control environmental conditions, such as air pressure and filtration to prevent contamination of the device and to provide proper conditions for each of the operations performed, as required by 21 CFR 820.46. For example:

a. There are no specifications for the replacement of air filters in the cleanroom. The filters were last replaced in 1994.

b. There is no written procedure or specification for monitoring positive air pressure in the cleanroom.

5. Failure to assure that all quality assurance checks are appropriate and adequate for their purpose and are performed correctly, as required by 21 CFR 820.20(a)(4). For example:

   a. Torque gauge M32 was identified as being "OK" even though its accuracy limit was exceeded.

   b. Micrometer M7 was not calibrated at the point which it is actually used ot make measurements.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all products manufactured, distributed, held, and labeled by Stockert Instruments, Gmbh., are in compliance with the provisions of the Act and regulations.

The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. Until these violations are corrected, Federal agencies will be advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for premarket approval (PMA) will be approved and no premarket notification (510(k)) will be found to be substantially equivalent until the above violations have been corrected.

Please notify this office in writing within 15 days after the receipt of this letter as to the specific steps you have taken, or intend to take, to correct these violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Please include any and all documentation to show that adequate corrections have been achieved. Please provide an English translation, or an English summary, of what the documents contain for all submitted documents. This will facilitate our review of your response. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. Please address your response to:

Ms. Mary Ann Fitzgerald
Food and Drug Administration
Center for Devices and Radiological Health
Office of Compliance
Division of Enforcement III
2098 Gaither Road
Rockville, Maryland 20850

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Fitzgerald by letter at the above address, by telephone at (301) 594-4648, or by FAX at (301) 594-4672.

Sincerely yours,

Gladys Fooks for.

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

cc: [redacted]